

Atty Dkt. No.: IRVN-005cip
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A4 DP 25. (New) The composition of claim 1, which is formulated for administration into a tumor or tumor bed, wherein administration of the composition into a tumor or tumor bed in the patient elicits an immunological response by the patient against the tumor.

DP 2. The composition of claim 1, comprising lymphocytes from at least two different humans. ≥ 2 donors

3. The composition of claim 2, comprising lymphocytes from at least three different humans. ≥ 3 donors

4. The composition of claim 3, comprising lymphocytes from at least four different humans. ≥ 4 donors

DP 5. The composition of claim 2, wherein lymphocytes from at least one of the humans is inactivated. Lymph inactive

6. The composition of claim 1, further comprising a tumor-associated antigen. TAA

A4 DP 26. (New) The composition of claim 6, which is formulated for subcutaneous or intramuscular administration, wherein administration of the composition at a site distal to the tumor elicits an immunological response by the patient against the tumor.

7. The composition of claim 6, wherein the tumor-associated antigen is expressed on a tumor cell present in the composition. TAA express on tumor

8. The composition of claim 1, wherein the lymphocytes are alloactivated by coculturing with human cells *ex vivo* expressing HLA-DR antigens that are allogeneic to both HLA-DR antigens on the lymphocytes. Activate by co-culture w/ HLA-Dr ag. allogeneic to Ag on lympho

DP 9. The composition of claim 1, wherein the lymphocytes are alloactivated by coculturing with allogeneic human cells *ex vivo* for a time whereby the lymphocytes become sufficiently alloactivated to be effective in eliciting an anti-tumor immunological response when administered to a human.

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10. The composition of claim 1, wherein the lymphocytes are alloactivated by coculturing with allogeneic human cells *ex vivo* for a time whereby the lymphocytes become sufficiently alloactivated to be effective in extending life expectancy or causing progressive reduction in tumor mass when administered to a human having a tumor. 103

^{DP}₄ 11. The composition of claim 1, wherein the lymphocytes are alloactivated by coculturing with allogeneic human cells *ex vivo* until about the time when secretion of IFN- γ by the alloactivated lymphocytes is highest. *secrete IFN γ*

12. The composition of claim 1, wherein the lymphocytes are alloactivated by coculturing with allogeneic human cells *ex vivo* until about the time when secretion of IL-2 by the alloactivated lymphocytes is highest. *secrete IL-2*

¹⁰³
A2 ^{DP}₄ 13. (Amended) The composition of claim 1, wherein the lymphocytes are alloactivated by coculturing with allogeneic human cells *ex vivo* for between about 12 hours and 5 days. *12 hr - 5 days*

^{DP}₄ 14. The composition of claim 1, wherein the lymphocytes are alloactivated by coculturing with allogeneic human cells *ex vivo* for between about 24 and 72 hours. *24 - 72 hrs*

A3 15. (Amended) A kit comprising components of the composition of claim 6 in separate containers.

16. A device for treatment of a tumor in a human patient, containing the composition of claim 1.

17. The device of claim 16, which is an injection needle.

18. The device of claim 16, which is suitable for positioning by ultrasound guided endoscopy.

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19. A method for treating cancer in a human patient, comprising administering to the patient the pharmaceutical composition of claim 1.
20. A method for eliciting an anti-tumor immunological response in a human patient, comprising administering to the patient the pharmaceutical composition of claim 1.
21. A method for treating cancer in a human patient, comprising administering to the patient the pharmaceutical composition of claim 6.
22. A method for eliciting an anti-tumor immunological response in a human patient, comprising administering to the patient the pharmaceutical composition of claim 6.
23. The method of claim 19, wherein the pharmaceutical composition is administered at or around the site of a solid tumor in the patient.
24. The method of claim 21, wherein the pharmaceutical composition is administered at a site distal to the tumor.

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1-26 are pending after entry of the amendments set forth herein.

Claims 1, 13 and 15 have been amended.

Support for the amendment to claim 1 is found in the specification at, for example, page 7, line 27 to page 8, line 3; and in the Examples (see, e.g., page 35, line 1 to page 39, line 15; page 46, line 17 to page 51, line 4; page 53, line 1 to page 58, line 15).

Claim 13 is amended to correct a typographical error.

Claim 15 is amended so as to depend from claim 1 rather than claim 6.

Support for new claim 25 is found in the specification at, for example, page 10, lines 9-11; and page 55, lines 11-16. Support for new claim 26 is found in, for example, the